

## **REMARKS**

### **Pending Claims**

Claim 1 has been amended. Claims 2-49 have been cancelled. New claims 50-73 have been added, with claims 60-73 withdrawn pending Notice of Allowance and rejoinder. No new matter has been introduced by way of this amendment. Entry of the Amendment and Allowance of claims 1 and 50-59 and rejoinder and allowance of claims 62-74 is respectfully requested.

### **Examiner Interview**

Applicants thank Examiner Ibrahim for her assistance and courtesy extended during recent telephonic interviews. The amended claims are consistent with those suggested by the Examiner to be allowable, pending further search of the claimed sequences. Product claims 62-73 marked "New and withdrawn" were also discussed as subject to rejoinder on indication of allowance of the pending claims. Entry and Allowance of claims 1, 50-59, and 62-74 is respectfully requested.

### **Restriction and Linking Claims**

Applicants assert the elected product group and new product claim 1 is properly linked to claims that recite a method of using the product of claim 1, as well as to claims drawn to combinations/subcombinations that require all the limitations of the claimed product of claim 1. The claimed malt (malted kernels or grain) and wort (mashed malted grain) are each part of the plant or portion of claim 1. The claimed beverages are products produced using the claimed plant or plant portion of claim 1. Accordingly, the malt, wort, and beverage claims, each requiring all the limitations of claim 1, are linked to claim 1 as products produced from the claimed plant and/or as combinations and/or subcombinations permitted by MPEP section 809. Allowance of the product claims 1 and 50-59 and rejoinder of the linked claims 62-73 is respectfully requested.

**Indefiniteness - 35 U.S.C. § 112, second paragraph**

The rejection of claims 3-5 as indefinite is rendered moot by the amendment of these claims. Removal of this rejection is requested.

**35 U.S.C. § 103 - *Rutgersson* with *Kleinhofs*:**

Claims 1-13 were rejected by the Examiner as obvious over *Rutgersson et al.*, 1997, in view of *Kleinhofs et al.*, 1978. Applicants respectfully traverse this rejection. *Rutgersson* teaches a method of soaking barley in lactic acid with heat to remove from the plant lipoxygenase and lipase activity. The reference teaches a non-specific method of inactivating LOX activity and other enzyme activities in a plant and fails to teach a specific, inheritable mutation of LOX-1 resulting in null activity as claimed.

The Examiner acknowledges that *Rutgersson* does not teach a barley plant with null LOX-1 activity. Combining *Kleinhofs*, a general reference teaching mutagenesis methods, the Examiner contends it would be obvious to modify the acid soaking method of inactivating lipoxygenase taught by *Rutgersson* to a method of inactivating lipoxygenase by gene mutagenesis, further asserting "the premature nonsense codon or splice site mutation in the LOX-1 is an inherent property of the LOX-1 mutant barley" (Office Action dated 04/23/07, page 5).

Applicants respectfully traverse this rejection. Neither the primary or secondary reference provides any specific suggestion to make thousands, if not hundreds of thousands, of mutations in genes encoding any one of LOX-1, LOX-2, LOX-3, lipases, or other enzymes impacted by the acid soaking method of *Rutgersson*. Nothing in the cited combination suggests that a null LOX-1 mutant as claimed can be achieved. Furthermore, to be an inherent property, the premature nonsense codon or splice site mutation resulting in null lox activity must necessarily be present in the disclosed mutation.

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *See* MPEP 2131.01, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The identical invention must be shown in the same complete detail as is recited by the claims. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. MPEP §2112. The Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). The prior inherent characteristic must be established as a certainty, probabilities are not sufficient. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981).

In the instant application, no specific mutation is enabled expressly or inherently in the cited combination. Removal of this rejection is requested

**35 U.S.C. § 103 - *Douma* WO02/053721:**

Claims 1-14 and 48-49 were rejected as obvious over the PCT publication of *Douma et al.*, WO02/053721. Applicants respectfully traverse this rejection.

WO02/053721 nowhere discloses in an enabling manner the generation and isolation of barley plants having a mutation in the LOX-1 gene causing total loss of LOX-1 function (null-LOX-1 barley plant). The barely plants described in WO02/053721 retain at least 10% LOX-1 activity as compared to the wild-type enzyme. See, for example, page 17, lines 18-25 and Figure 13 of the present application.

As explained in the prior response, not a single null-LOX-1 barley plant was identified in the cited reference after screening as many as 20,000 mutagenized barley plants. Further, the reference describes a mutation frequency of 0.9-2.3 per 10,000 grains was expected, based on a study by Kleinhof *et al.*, 1978, where a mutation frequency of 1 to 2.7 was observed in barley after mutagenesis with azide. Thus, it was expected that in the range of 2 to 5 null-Lox-1 barley plants would be identified after screening 20,000 plants. However, not a single null-LOX-1

mutant was identified. This implies that it is highly unlikely that a null-LOX-1 barley plant can be identified by the methods described.

In contrast, the instant application provides two null-lox mutants as well as a new and efficient screening method that permits a reproducible identification of barley plants with null LOX-1 activity (see, for example, p.34, l. 23-29). According to the present application, kernels or preferably embryos, for example of an M2 or higher generation when used for screening provide an improved assay method (p.34, l. 27-29; P. 36, l. 16-20). Using the new and efficient screening methods, two different null-LOX-1 mutants were identified by screening less than 15,000 mutagenized barley plants (See Example 1, page 60). In the absence of any specific enabling teaching how to achieve barley plants with a total loss of function of LOX-1 (null LOX-1 activity), the reference fails to do more than invite undue experimentation.

For at least the reasons discussed above, Applicants assert the claims are not rendered obvious by *Douma* WO02/053721. Removal of this rejection is requested.

### **Double patenting**

The claims of US 6,660,915 relate to barley plants and parts of the plant carrying a specific mutation in the LOX-1 gene identified by SEQ ID 12 of the patent, plant products prepared from such barley plants, as well as to methods for producing beer or other beverages using such barley plants. As is apparent from Figure 13 of US 6,660,915, the LOX-1 activity of a barley plant carrying this specific mutation is at least 10% compared to wild type. Accordingly, such barley plants fail to teach or suggest null-LOX-1 activity barley plants nor methods to produce such null LOX-1 plants as claimed. For at least these reasons, Applicants respectfully request removal of the double patenting rejection.

### Conclusion

In light of the forgoing Amendment and Remarks, Applicant's respectfully assert the claims are in condition for allowance. Early notice of such allowance is solicited.

The Examiner is invited to telephone the undersigned attorney for clarification of any of these remarks and/or to otherwise speed prosecution of this case.

Respectfully submitted,

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